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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,421	03/25/2005	Andreas Meyer	PC/4-32584A	8057

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
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EXAMINER	
THOMAS, TIMOTHY P	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
09/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,421	MEYER ET AL.	
	Examiner	Art Unit	
	Timothy P. Thomas	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-26* is/are pending in the application.

4a) Of the above claim(s) *17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 19-26* is/are rejected.

7)☒ Claim(s) *1-16 and 19-26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/9/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-17 and 19-24, in the reply filed on 8/9/2007 is acknowledged.

2. Applicant's election without traverse of specie of Example 4; the HMG-CoA reductase inhibitor is pitavastatin Ca-salt; at least one matrix former is HPMC in the reply filed on 8/9/2007 is acknowledged.

3. Claims 17-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/9/2007. It is noted that applicant has requested the rejoinder of claim 17, if the pharmaceutical composition is found to be novel, and an expanded search beyond example 4, if the species is found to be novel.

Status of Claims

4. Acknowledgement is made of the amended claims filed with the response of 8/9/2007. Claim 18 is cancelled. Claim 17 is withdrawn. New claims 25-26 have been added. Claims 1-17 and 19-26 are pending. Claims 1-16 and 19-26 are examined on the basis of the merits.

Specification

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract

on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

6. The abstract of the disclosure is objected to because the use of legal phraseology, "comprising" (2nd line), "said" (line 2), and "comprises" (3rd line). Correction is required. See MPEP § 608.01(b).

Claim Objections

7. Claims 11, 19, 22 and 24 are Claims 11, 19, 22 and 24 are objected to because of the following informalities: claims 11 and 24 are missing the word "and" in the 3rd line, between the last two members of the matrix former group members. Claim 19 is missing the word "to" between "according" and "claim 3" in the first line. Claim 22 is missing a period at the end of the claim. Appropriate correction is required.

8. Claim 19 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 18. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-16 and 19-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear whether the terms in parenthesis in claim 1 are intended to further limit the subject matter of the claim or just to provide alternate terminology.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-16 and 19-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Tanizawa et al. (US 2004/0018234 A1; priority claim 6/17/2002; previously listed on PTO-892).

Tanizawa teaches pharmaceutical compositions containing pitavastatin and at least two layers, which release the drug rapidly in the stomach, and an enteric component, which releases a portion of the drug slowly (abstract); the Ca-salt of pitavastatin (paragraph 0068); HPMC as a sustained release component (matrix former) is present in at least the outer phase, as well as the inner phase (paragraph 0032, 0036, 0041, 0042, example 1); the pitavastatin amount of 6.25 weight % may be calculated from the amounts taught in example 1 ((12.00+4.00)/256.00); pitavastatin doses include

the preferable range 1-32 mg (paragraph 0065) and 16 mg (example 1, Table 2); HPMC is present at 9.375 wt % (Table 2); magnesium alumino metasilicate (stabilizer) is taught at 1.25 wt % (Table 2); more than one type of matrix former component is taught (Tables 5, 7), these components are distinct and, absent evidence to the contrary, have different viscosities. It is noted that Tanizawa does not specify the viscosities of the matrix formers used in the different phases. The HPMC taught by Tanizawa in the inner phase of example 1 (TC-5R) has been reported to have a viscosity of 6 cps (6 mPa s) in a 2 wt % aqueous solution (Sugihara, et al.; US 20040213845 A1; paragraph 0077). Considering the many different compounds taught by Tanizawa that may be categorized as matrix formers in the external phase (e.g., paragraphs 0025-0042; for a pitavastatin-containing composition coated with the sustained release component), the coating materials range from oils to waxes, and cover the range of viscosities of the matrix formers required by the instant claim 10.

13. Claims 1-5, 9, 11-14, 19-21, and 23-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Tillyer, et al. (US 2003/0211151 A1; priority date 03/1999).

Tillyer teaches pharmaceutical compositions containing an HMG-CoA reductase inhibitor and delayed-release dosage forms with two or more layers (abstract; paragraph 0042); HMG-CoA reductase inhibitor species includes nisvastatin or NK-104 (pitavastatin) and the calcium salt (paragraphs 0028, 0029); stability of the statin is enhanced by sub-coating with 1:1 hydroxypropyl cellulose:hydroxypropyl methyl cellulose mixture, covered by a polymeric outer coating (paragraph 0043; example 19; claim 40); statin dosages include values in the range of 5 mg-25 mg (paragraph 0067);

stabilizing agents are taught (paragraph 0071); the outer coating is taught to correspond to a 5-15%, e.g., 10% weight gain, a similar weight is implied for the sub-coating (paragraph 0043; examples 18-19) (i.e., HMPC would be 2.5-7.5 or about 5%).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1-14, 16, and 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alberts, et al. (EP 0 465 096 A1; 1992).

Alberts teaches compositions with an HMG-CoA reductase inhibitor in sustained-release formulations (abstract; p. 3, lines 7-10); pravastatin is taught as an HMG-CoA reductase inhibitor (p. 2, lines 5-8); coated tablets are taught with a matrix-delivery system, containing simvastatin and HPMC and hydroxypropylcellulose (HPC) or HPC in an inner phase and a film coat (outer phase) comprising HPMC (6 cps) and HPC (examples 11-16); different forms of HPMC (with different viscosities) are taught (examples 12-14); magnesium stearate and ascorbic acid are taught (stabilizers); using the values for example 14, simvastatin is 7.99%, HPMC is 32.6%, stabilizers are 2.7% of the formulation. Alberts does not teach a composition with pitavastatin along with HPMC in an outer phase in the same composition. It would have been obvious to one skilled in the art at the time of the invention to substitute pitavastatin for simvastatin in the formulations of examples 11-16 to form the compositions of the instant claims, with an expectation of success. The motivation to do so would be to prepare a sustained-release formulation of an alternate HMG-CoA inhibitor drug. It would also have been obvious to substitute an HPMC with higher molecular weight (viscosity in the 100-100000 cps range) in the outer phase. The motivation to do so is suggested by Alberts (example 11, lines 23-25), to prepare a slower-release form of the composition.

Conclusion

18. No claims are allowed.

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 2003/0176501 A1; US 2003/0180352 A1; WO 98/15264 (IDS reference, filed 8/9/2005).

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy P. Thomas whose telephone number is (571) 272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ardin H. Marschel 9/12/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

/TPT/
Timothy P. Thomas
Patent Examiner